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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/518,074   | 12/16/2004  | Ian-Lucas Gatfield   | 47939               | 5552             |
| ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W. SUITE 600 WASHINGTON,, DC 20036 |             |                      | EXAMINER            |                  |
|  |             |                      | CARR, DEBORAH D     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1621                |                  |
|  |             |                      |                     |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 06/17/2008          | PAPER            |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)      |  |  |  |  |
|--|---|-------------------|--|--|--|--|
| Office Action Comments   | 10/518,074  | GATFIELD ET AL.   |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit          |  |  |  |  |
|  | DEBORAH D. CARR   | 1621              |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |                   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                   |  |  |  |  |
| Status   |   |                   |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>24 Ja</u>   | nuary 2008  |                   |  |  |  |  |
|  | action is non-final.  |                   |  |  |  |  |
| ·=   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                   |  |  |  |  |
|  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.               |                   |  |  |  |  |
|  | parto Quayro, 1000 0.5. 11, 10  | 0.0.210.          |  |  |  |  |
| Disposition of Claims  |   |                   |  |  |  |  |
| 4) Claim(s) <u>1-19</u> is/are pending in the application.   | 4) Claim(s) <u>1-19</u> is/are pending in the application.  |                   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                   |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                   |  |  |  |  |
| 6)⊠ Claim(s) <u>1-19</u> is/are rejected.  |   |                   |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                   |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | election requirement.   |                   |  |  |  |  |
| Application Papers   |   |                   |  |  |  |  |
|  |   |                   |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |                   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                   |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                   |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some coll None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                   |  |  |  |  |
| Attachment(s)  1) \[ \sum \text{Notice of References Cited (PTO-892)} \]   | 4) ☐ Interview Summary  | (PTO-413)         |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date   |                   |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)   | 5) Notice of Informal P   | atent Application |  |  |  |  |
| Paper No(s)/Mail Date 6) L Other:  |   |                   |  |  |  |  |

#### **DETAILED ACTION**

## Response to Arguments

1. Applicant's arguments filed 24 January 2008 regarding the rejection of claim 1 under 35USC§103 and claims 1-14 rejected provisionally under the judicially created doctrine of obviousness-type double patenting have been fully considered but they are not persuasive.

## Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12 of copending

Application No. 10/483,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method for imparting a salivation inducing effect to a foodstuff preparation or an oral hygiene preparation by adding cispellitorin is claimed. Although each set of claims refer to different stereoisomers, it is reasonable to expect a similar saliva-inducing property with each.

A novel useful compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. In re Norris, 179 F.2d. 970, 84 USPQ 458 (CCPA 1970). Therefore, it would have been obvious to one of ordinary skill to expect similar properties of structurally similar compounds since they are suggestive of one another. It has been held that a compound, which is structurally isomeric with a compound of the prior art, is prima facie obvious absent unexpected results. In re Finely, 81 USPQ 383 (CCPA 1949); 84 USPQ 458 (CCPA 1950).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues the following:

 The instant compounds are not stereoisomers of the compounds disclosed in 10/483,668.

- The properties of the compounds cannot be considered transferable because transpellitorin causes salivation and cis-pellitorin has a pungent taste.
- Based on the percentage of trans-pellitorin used to induce salivation, one would not use the amount of cis-pellitorin to obtain the sensory agent of the instant invention.

#### Examiner's response

• Stereoisomers fall into two broad classes: optical isomers and geometric (cistrans) isomers. Geometric isomers are a type of stereoisomerism in which a chemical group or atom occupies different spatial positions in relation to the double bonds. If the double bond is between two carbon atoms, the isomers are called cis and trans (Lewis, Richard J., Sr. (2002). Hawley's Condensed Chemical Dictionary (14th Edition). John Wiley & Sons.)

Applicant contrasts cis-pellitorin to the isomeric 2E,4E-decadienoic acid-N-isobutylamide on page 5, lines9-10 in the specification. Based on applicants interpretation and the definition given in Hawley's Condensed Chemical Dictionary, the examiner was correct in stating cis-pellitorin and trans-pellitorin are stereoisomers.

• Trans-pellitorin vs. Cis-pellitorin

Both compounds express salivating and pungency as being pellitorin based. The only difference between the compounds is how much of these characteristics are expressed in each compounds. Therefore, one of ordinary skill in the art based on what is

of a pungent taste over trans-pellitorin, which exhibits more of a salivating effect.

Examiner note that it is obvious to optimize the amount at which trans-pellitorin and cis-pellitorin are added to the food composition so as to effectively reduce or eliminate the unwanted numbing, burning, and spicy hot sensations because it was known at the time of the invention that trans-pellitorin and cis-pellitorin causes these sensations.

# Claim Rejections ~ 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1& 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al.

Applicant argues the following:

Contrary to the suggestion in the Action, the starting products and the process of
Tanaka et al. are not analogous with the claimed process or starting products.
 The process disclosed in Tanaka et al. specifically discloses the ethyl (2E, 4E)
decadienoate as a precursor for the synthesis of pellitorine as an insecticidal
compound.

• Moreover, the process disclosed in Tanaka et al. specifically carries out the alkaline hydrolysis of the ethyl (2E, 4E) decadienoate to produce the pure acid identified as Compound VII. The pure acid Compound VII is then reacted with isobutyl amine in the presence of diethyl phosphorocyanidate in DMF to produce the pure pellitorine. There is no suggestion in Tanaka et al. of reacting the 2E, 4Z-decadiene acid ester with isobutyl amine in the presence of a catalyst. Moreover, Tanaka et al. clearly fails to disclose or suggest a catalyst, which is capable of carrying out the reaction of the ester with isobutyl amine as in the claimed invention.

## Examiner's response

Ethyl (2E, 4E) decadienoate as disclosed by Tanaka is the ethyl ester derivative of (2E, 4E) decadienoic acid which is analogous to the ethyl ester derivative of (2E, 4E) decadienoic acid in that they are both dienes. It has been determined that the mere use of different starting materials, whether novel or known, in a conventional process to produce the product one would expect therefrom does not render the process unobvious. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose.

Once the general reaction has been shown to be old, burden is on the applicant to present reason or authority for believing that a group on the starting compound would

take part in or affect the basic reaction and thus alter the nature of the product or operability of the process. Applicant have not proven that the placement of the double bonds would in anyway hinder the process as disclosed by Tanaka the conversion of the ester group to an carboxamide group.

Diethyl phosphorocyanidate in DMF is present as a catalyst in the reaction of VII with isobutyl amine. As to ethyl (2E, 4E) decadienoate only being a precursor for the synthesis of pellitorine as an insecticidal compound, pellitorin was originally discovered in Anacyclus pyrethrum. Anacyclus pyrethrum have been used in medicine since Dioscorides (an ancient Greek physician, pharmacologist and botanist from Anazarbus, Cilicia, Asia Minor, who practiced in ancient Rome during the time of Nero, famous for writing a five volume book De Materia Medica that is a precursor to all modern pharmacopoeias, and is one of the most influential herbal books in history).

Therefore, to argue the compounds disclosed by Tanaka et al are only insecticides and do not exhibit sensory properties is unsubstantiated.

#### Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571–272–0871. The fax phone number for the organization where this application or proceeding is assigned is 571–273–8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have guestions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

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Representative or access to the automated information system, call 800-786-9199 (IN

USA OR CANADA) or 571-272-1000.

/Deborah D Carr/ Primary Examiner Art Unit 1621

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